Head and Neck Biomarker Reporting Template

Version: 2.0.0.1
Protocol Posting Date: November 2021
The use of this protocol is recommended for clinical care purposes but is not required for accreditation purposes.

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With guidance from the CAP Cancer and CAP Pathology Electronic Reporting Committees.
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Accreditation Requirements
Completion of the template is the responsibility of the laboratory performing the biomarker testing and/or providing the interpretation. When both testing and interpretation are performed elsewhere (eg, a reference laboratory), synoptic reporting of the results by the laboratory submitting the tissue for testing is also encouraged to ensure that all information is included in the patient’s medical record and thus readily available to the treating clinical team. This template is not required for accreditation purposes.

Summary of Changes

v 2.0.0.1
• The CAP made no changes to Cancer Protocol content. We updated metadata only for the electronic Cancer Checklists (eCC), requiring a version number change for the Word and PDF Cancer Protocols.
Reporting Template

Protocol Posting Date: November 2021
Select a single response unless otherwise indicated.

CASE SUMMARY: (Head and Neck Biomarker Reporting)

MORPHOLOGIC DIAGNOSIS

+Diagnosis: _________________

RESULTS

Head and Neck Squamous Cell Carcinoma (HNSCC)
Human Papillomavirus (HPV) Testing

+p16 IHC as a Surrogate for Transcriptionally Active High-Risk HPV

___ Negative (less than 50% diffuse and moderate-to-strong nuclear and cytoplasmic staining)
___ Equivocal (less than 70% but greater than 50% diffuse and moderate-to-strong nuclear and cytoplasmic staining)
___ Positive (greater than or equal to 70% diffuse and moderate-to-strong nuclear and cytoplasmic staining)
___ Other results (including cytology specimens, specify): _________________
___ Cannot be determined (explain): _________________

+HPV E6/E7 mRNA ISH

___ Negative (no signal)
___ Positive (cytoplasmic and/or nuclear signals)

+Specify Subtypes (if available): _________________
___ Cannot be determined (explain): _________________

+HPV-DNA ISH

___ Negative (no nuclear signal)
___ Positive (punctate and/or diffuse nuclear staining)

+Specify Subtypes (if available): _________________
___ Cannot be determined (explain): _________________

+HPV-DNA PCR

___ Negative (no signal)
___ Positive (cytoplasmic and/or nuclear signals)

+Specify Subtypes (if available): _________________
___ Cannot be determined (explain): _________________

+HPV E6/E7 mRNA RT-PCR

___ Negative (no signal)
___ Positive (cytoplasmic and/or nuclear signals)

+Specify Subtypes (if available): _________________
___ Cannot be determined (explain): _________________
Epstein-Barr Virus (EBV) Testing
+EBV Early mRNA (EBER) ISH
  ___ Negative (no signal)
  ___ Positive (nuclear signal)
  ___ Cannot be determined (explain): _________________

NUT Midline Carcinoma
+NUT IHC
  ___ Negative (no nuclear staining)
  ___ Positive (nuclear staining)
  ___ Cannot be determined (explain): _________________

+NUT Rearrangements (by Molecular Methods)
  ___ No NUT rearrangement detected
  ___ NUT rearrangement detected
  +Specify Fusion Partner (if available): _________________
  ___ Cannot be determined (explain): _________________

Salivary Gland Carcinoma
Mucoepidermoid Carcinoma
+MAML2 Rearrangements (by Molecular Methods)
  ___ No MAML2 rearrangement detected
  ___ MAML2 rearrangement detected
  +Specify Fusion Partner (if available): _________________
  ___ Cannot be determined (explain): _________________

Adenoid Cystic Carcinoma
+MYB IHC
  ___ Negative (no nuclear staining)
  ___ Positive (nuclear staining)
  ___ Cannot be determined (explain): _________________

+MYB Rearrangements (by Molecular Methods)
  ___ No MYB rearrangement detected
  ___ MYB rearrangement detected
  +Specify Fusion Partner (if available): _________________
  ___ Cannot be determined (explain): _________________

+MYB-L1 IHC
  ___ Negative (no nuclear staining)
  ___ Positive (nuclear staining)
  ___ Cannot be determined (explain): _________________

+MYB-L1 Rearrangements (by Molecular Methods)
  ___ No MYB-L1 rearrangement detected
  ___ MYB-L1 rearrangement detected
  +Specify Fusion Partner (if available): _________________
  ___ Cannot be determined (explain): _________________
Salivary Duct Carcinoma

**+AR IHC**
- Negative (no nuclear staining)
- Positive (nuclear staining)
- Cannot be determined (explain): ____________________

**+HER2 Immunohistochemistry Interpretation**
- Negative
- Equivocal
- Positive

**+HER2 Immunohistochemistry Scoring System**
- Breast
- Gastric
- Other (specify): ____________________

**+HER2 Immunohistochemistry Score**
- 0
- 1+
- 2+
- 3+
- Other (specify): ____________________

**Specify Percentage of Cells with Uniform Intense Complete Membrane Staining:** ____________________ %

**+HER2 Immunohistochemistry Antibody**
- HercepTest
- 4B5
- SP3
- Other (specify): ____________________

**+HER2 Immunohistochemistry Assay Information**
- Food and Drug Administration (FDA) cleared test / vendor (specify): ____________________
- Laboratory-developed test

**+HER2 by in situ Hybridization**
- Negative (not amplified)
- Positive (amplified)
- Cannot be determined (indeterminate) (explain): ____________________

**Aneusomy (as defined by vendor kit used)**
- Not identified
- Present (explain): ____________________

**Heterogeneous Signals**
- Not identified
- Present
+Specify Percentage of Cells with Amplified HER2 Signals: _________________ %

Carcinoma ex Pleomorphic Adenoma / Pleomorphic Adenoma

+PLAG1 IHC
___ Negative (no nuclear staining)
___ Positive (nuclear staining)
___ Cannot be determined (explain): _________________

+PLAG1 Rearrangements (by Molecular Methods)
___ No PLAG1 rearrangement detected
___ PLAG1 rearrangement detected
___ Cannot be determined (explain): _________________

+Specify Fusion Partner (if available): _________________

+HMGA2 IHC
___ Negative (no nuclear staining)
___ Positive (nuclear staining)
___ Cannot be determined (explain): _________________

+HMGA2 Rearrangements (by Molecular Methods)
___ No HMGA2 rearrangement detected
___ HMGA2 rearrangement detected
___ Cannot be determined (explain): _________________

+Specify Fusion Partner (if available): _________________

(Mammary Analogue) Secretory Carcinoma

+ETV6 Rearrangements (by Molecular Methods)
___ No ETV6 rearrangement detected
___ ETV6 rearrangement detected
___ Cannot be determined (explain): _________________

+Specify Fusion Partner (if available): _________________

+NTRK Rearrangements (by Molecular Methods)
___ NTRK rearrangement detected

+NTRK Type
___ NTRK1
___ NTRK2
___ NTRK3
___ Cannot be determined (explain): _________________

+Specify Fusion Partner (if available): _________________

+NTRK Type
___ NTRK1
___ NTRK2
___ NTRK3
___ Cannot be determined (explain): _________________

(Hyalinizing) Clear Cell Carcinoma

+EWSR1 Rearrangements (by Molecular Methods)
___ No EWSR1 rearrangement detected
___ EWSR1 rearrangement detected
___ Cannot be determined (explain): _________________

+Specify Fusion Partner (if available): _________________
Sinonasal Malignancies
SMARCB1 (INI-1) and SMARCA4 (BRG-1) Deficient Sinonasal Carcinoma/Rhabdoid Tumor / Teratocarcinosarcoma

+INI1 IHC
___ Intact nuclear staining (negative for deletion / alteration)
___ Loss of nuclear staining (positive for deletion / alteration)
___ Cannot be determined (explain): _________________

+BRG1 IHC
___ Intact nuclear staining (negative for deletion / alteration)
___ Loss of nuclear staining (positive for deletion / alteration)
___ Cannot be determined (explain): _________________

Biphenotypic Sinonasal Sarcoma
+PAX Rearrangements (by Molecular Methods)
___ PAX rearrangement detected

+PAX Type
___ PAX3
___ PAX7

+Specify Fusion Partner (if available): _________________
___ No PAX rearrangement detected
___ Cannot be determined (explain): _________________

Paraganglioma
+SDHB IHC
___ Intact cytoplasmic staining
___ Loss of cytoplasmic staining
___ Cannot be determined (explain): _________________

Other Markers (repeat up to 10X, as needed)
+Specify Other Marker and Results: _________________

COMMENTS

Comment(s): _________________